IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	)	
Plaintiff,	)	
vs.	)	**Case No. 2:24-cv-04144-MDH**
ANDREW BAILEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MISSOURI; JAMES L. GRAY, in his official capacity as President of the Missouri Board of Pharmacy; CHRISTAN S. TADRUS, in his official capacity as Vice-President of the Missouri Board of Pharmacy; and DOUGLAS R. LANG, ANITA K. PARRAN, COLBY GROVE, TAMMY THOMPSON, and DARREN HARRIS, in their official capacities as members of the Missouri Board of Pharmacy,	)	
Defendants.	)	
v.	)	
MISSOURI HOSPTIAL ASSOCIATION, And MISSOURI PRIMARY CARE ASSOCIATION,	)	
Intervenors	)	

ORDER

Before the Court are State Defendant's Motion to Dismiss for Failure to State a Claim. (Doc. 68) and Intervenor's Motion to Dismiss for Failure to State a Claim. (Doc. 66). Plaintiff has filed its suggestions in opposition. (Doc 84). Both State Defendants and Intervenor Defendants (collectively "Defendants") have filed their replies. (Docs. 86 and 87). The matter is now ripe for

adjudication. For reasons herein, Defendants' Motions are **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

This case arises out of Senate Bill ("S.B.") 751 which created protections to the delivery of 340B drugs to contract pharmacies on behalf of "covered entities". Section 340B incentivizes pharmaceutical manufactures to provide qualified health care providers, referred to as "covered entities," with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. Covered entities have contracted with outside pharmacies or "contract pharmacies," for the distribution and dispensation of 340B drugs. S.B. 751 protects hospitals, federal qualified health centers ("FQHC"), and their patients from drug manufacturers' restrictions on the number of contract pharmacies a hospital or FQHC can use and still receive discount pricing under 340B plan. Plaintiff is a trade association with its headquarters and principal place of business in Washington, D.C. Defendants are all residents of Missouri that are responsible for administering and enforcing the provisions of S.B. 751. Intervenors Missouri Hospital Association and Missouri Primary Care Association are Missouri, not-for-profit member organizations.

Plaintiff alleges three Counts seeking declaratory relief that S.B. 751 is unconstitutional and injunctive relief barring enforcement of S.B. 751. Count I alleges S.B. 751 is preempted by the Supremacy Clause based on claims data policies. Count II alleges S.B. 751 is preempted by federal 340B law and the Supremacy Clause based on contract pharmacy policies. Count III alleges S.B. 751 is preempted generally under the Supremacy Clause and the federal 340B statute. Lastly, Count IV alleges S.B. 751 is an unconstitutional extraterritorial regulation. Defendants argue S.B.

751 is not preempted based on Eighth Circuit precedent in *Pharm. Rsch. & Manufacturers of Am. v. McClain* and that S.B. 751 does not apply exterritorialy.

STANDARD OF REVIEW

A complaint must contain factual allegations that, when accepted as true, are sufficient to state a claim of relief that is plausible on its face. *Zutz v. Nelson*, 601 F.3d 842, 848 (8th Cir. 2010) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The Court "must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005) (internal citations omitted). The complaint's factual allegations must be sufficient to "raise a right to relief above the speculative level," and the motion to dismiss must be granted if the complaint does not contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 545 (2007). Further, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. *Ashcroft*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

ANALYSIS

I. Count I – Conflict Preemption Under the Supremacy Clause of the U.S. Constitution – Claims Data Policies

Count I seeks declaratory and injunctive relief claiming S.B. 751 is conflict preempted by claims data policies under federal law. Specifically, that manufactures are permitted to require certain types of data as a precondition of their "offer" to provide 340B priced drugs to covered entities. Defendants argue that the 340B statute does not control claims data policies, and state may regulate in that empty space.

"Article VI of the Constitution provides that the laws of the United States 'shall be the supreme Law of the Land; … any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.'" U.S. Const. art. VI, cl. 2. State laws that conflict with federal law are "without effect." *Cipollone v. Liggett grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, L.Ed.2d 407 (1992). Congress may preempt a state law through federal legislation, but where a federal statute does not refer expressly to preemption, Congress may implicitly preempt a state law. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015). Congress may impliedly pre-empt state law "either through 'field' preemption or "conflict' preemption." *Id*. Conflict pre-emption exists where 'compliance with both state and federal law is impossible,' or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objections of Congress.'" *Id*. (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989).

Plaintiff argues that the federal 340B statutes requires only that manufacturers "offer' 340B priced drugs to covered entities. (Complaint ¶ 122). Plaintiff assets multiple courts have concluded that manufacturers may impose reasonable conditions on their offers of 340B priced drugs that require covered entities and contract pharmacies to provide certain claims data related to restrictions that were purportedly dispensed as 340B drugs. *Id*. If a potential buyer will not agree to a manufacturer claims data requirement in the offer, there is no offer and acceptance, and thus no "purchase" of a 340B drug by a covered entity under federal law. (Complaint ¶ 123). As such the 340B pricing requirement does not apply under federal law. *Id*. Plaintiff thus asserts that S.B. 751 mandates the 340B pricing obligation even where the federal statute does not and is therefore a conflict with the federal law. (Complaint ¶ 124). Plaintiff lastly asserts that S.B. 751's restrictions also impermissibly limit drug manufacturers' ability to utilize the federal enforcement scheme and

will contribute to duplicate discounts and diversion of 340B drugs to ineligible recipients. (Complaint ¶¶ 126-127).

Under Eighth Circuit precedent the 340B program "is silent about delivery" and distribution of pharmaceuticals to patients. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136, 1142 (8th Cir. 2024), cert. denied, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024) (quoting *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d. Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). The 340B program is not "so pervasive … that Congress left no room for the States to supplement it. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136 (8th Cir. 2024) at 1144 (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). The Eighth Circuit reasoned that pharmacies have always been an essential part of the 340B program and Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field. *Id*. The practice of pharmacy is an area traditionally left to state regulation and that the case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest and has nonetheless decided to stand by both concept and to tolerate whatever tension there [is] between them." *Id*.

Taking Plaintiff's allegations as true for the purposes of a motion to dismiss it has failed to show a right to relief above a speculative level. Here, the federal 340B program was silent as to delivery of 340B drugs and thus drug manufacturers were able to impose conditions. However, S.B. 751 restricts pharmaceutical companies from infringing on the distribution and delivery of 340B drugs bought by covered entitles utilizing the 340B program. Missouri in enacting S.B. 751 was allowed to promulgate rules concerning the delivery and acquisition of 340B drugs based on

the silence of the federal 340B program and because the practice of pharmacy is traditionally left to state regulation. This includes terms regarding the claim data policies.

Plaintiff's claim that S.B. 751's restrictions also impermissibly limit drug manufacturers' ability to utilize the federal enforcement scheme also fails to raise a right of relief above a speculative level. 42 U.S.C. § 256b puts limitation on prices of drugs purchased by covered entities. Specifically, 42 U.S.C. §256b(a)(5)(C) details the process for the Secretary of Health and Human Services or a drug manufacturer on the process to audit a covered entity. "A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug with the entity to audit at the Secretary's or the manufacturer's expense the records of the entity." 42 U.S.C. § 256b(a)(5)(C). The federal 340B law creates an auditing scheme that allows any drug manufacturer to be able to audit a covered entity. S.B. 751 does nothing to change how audits are conducted on covered entities and claims data polices that condition the sale of 340B drugs on transfer of data collected at the expenses and effort of covered entities would be directly contrary to the 340B statutes provision that audits occur only at the expense of the Secretary or manufacturer. For the reasons stated, Defendants' Motion to Dismiss Count I is **GRANTED**.

II. Count II – Conflict Preemption Under the Supremacy clause of the U.S. Constitution and the Federal 340B Statute – Contract Pharmacy Policies

Count II seeks declaratory and injunctive relief claiming S.B. 751 is conflict preempted by the federal 340B law under the Supremacy Clause with respect to contract pharmacy policies. Specifically, Plaintiff alleges S.B. 751 mandates that manufacturers provide the 340B priced drugs to any and all contract pharmacies that a covered entity choses to contract with, which expands drug manufacturers' obligations under the federal program and conflicts with the original scope of

those obligations. Defendants argue that Count II should be dismissed because the Eighth Circuit in *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024) has held restrictions on drug manufacturers contract policies was not conflict preempted by federal 340B law.

"Where state and federal law 'directly conflict,' state law must give way. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011). Obstacle preemption exists where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000). What qualifies as "a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Id*. "If the purpose of the act cannot otherwise be accomplished–if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect–the state law must yield to the regulation of Congress within the sphere of its delegated power." *Id*.

Plaintiff argues that Congress imposes a requirement to "offer" 340B priced drugs on manufacturers and as part of the federal offer manufacturers may include limitations on the use of contract pharmacies. (Complaint ¶ 131). Plaintiff states the 340B pricing obligation attaches only where covered entities accept the terms of the offer. *Id*. Plaintiff argues that by mandating that manufacturers provide 340B priced drugs to all contract pharmacies that a covered entity choses to contract with, the Missouri statute dramatically expands manufacturers' obligations under the federal program and directly conflicts with the scope of those obligations. (Complaint ¶ 132). Plaintiff contends S.B. 751 extends the pricing to contract pharmacies even when the covered entity has not "purchased" a covered drug under federal law and a manufacturer therefore has no federal obligation to provide 340B pricing. (Complaint ¶ 134). Lastly, Plaintiff asserts S.B. 751's

state-law enforcement provision also conflicts with the calibrated system created by Congress to ensure 340B compliance. (Complaint ¶ 136).

A similar argument was made in *McClain*. The Eighth Circuit ruled the Arkansas law did not require manufactures to provide 340B pricing discounts to contract pharmacies nor does the state statue set or enforce discount pricing revealing create no obstacle to the enforce of the 340B program. *McClain at 1145.* Additionally, the Arkansas law's enforcement scheme is in place to deter pharmaceutical manufactures from interfering with a covered entity's contact pharmacy arrangements and again creates no obstacle for pharmaceutical manufactures to comply with both the state statute and Section 340B. *Id*.

Here, S.B. 751 does not require manufacturers to extend the federal 340B discount to contract pharmacies, it just restricts pharmaceutical companies from infringing on the distribution and delivery of 340B drugs bought by covered entitles utilizing the 340B program. S.B. 751 does not set or enforce discount pricing but protects covered entities use of contract pharmacies. As such, there is no obstacle to the enforcement of the 340B program. Likewise, S.B. 751 creates an enforcement scheme that makes any violation of a pharmaceutical manufacturer or third-party logistics provider an unlawful practice. Mo. Rev. Stat. § 376.414.3. It details the appropriate statutes should a violation happen to obtain compliance through monetary penalties and equitable relief.[1] *Id*. Consistent with the precedent set by the Eighth Circuit, Plaintiff has failed to allege a claim upon which relief can be granted. For the reasons stated, Defendants' Motion to Dismiss Count II as it relates to obstacle preemption is **GRANTED**. Count II is **DISMISSED** in its entirety.

[1] Mo. Rev. Stat. § 376.414.3 provides any act prohibited by subsection shall constitute an unlawful practice which any action may be authorized under Mo. Rev. Stat. §§ 407.010-407.130. Particularly relevant is Mo. Rev. Stat. § 407.100 which details remedies from the court such as restitution, civil penalties of not more than $1000.00 per violation, injunctions, temporary restraining orders, and other remedies.

III. Count III – Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute – Preemption Generally

Count III seeks declaratory and injunctive relief claiming S.B. 751 is conflict and field preempted by the Federal 340B Law under the Supremacy Clause. Defendants argue that Count III should be dismissed because the Eighth Circuit in *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024) has held an analogous Arkansas statute was not field nor conflict preempted by federal 340B law.

A. Field Preemption

When a federal regulatory scheme occupies the field because of its pervasive nature, leaving no room for state action, field preemption applies. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). Field preemption also applies when Congress "intend[s] 'to foreclose any state regulation in the [regulated] are,' irrespective of whether state law is consistent or inconsistent with 'federal standards.'" *Oneok, Inc.*, 575 U.S. at 377, 135 S.Ct. 1591 (quoting *Arizona v. United States*, 567 U.S. 387, 401, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012)). Congress's intent to preempt a field "can be inferred from a framework of regulation 'so pervasive … that Congress left no room for the States to supplement it' or a "federal interest … so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399, 132 S.Ct. 2492 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

Under Eighth Circuit precedent the 340B program is not "so pervasive … that Congress left no room for the States to supplement it. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136 (8th Cir. 2024) at 1144 (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). The Eighth Circuit reasoned that pharmacies have always

been an essential part of the 340B program and Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field. *Id*. The practice of pharmacy is an area traditionally left to state regulation and that the case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest and has nonetheless decided to stand by both concept and to tolerate whatever tension there [is] between them." *Id*. Further, the Eighth Circuit analyzed the difference between a state statute that ensures an oversight and enforcement scheme in promoting its protections for covered entities to distribute 340B compared to the federal 340B Program and its means for enforcement of discount prices. *Id*. The Eighth Circuit found that a statute which establishes enforcement for the distribution of 340B drugs and the federal 340B law's enforcement scheme address two completely different issues and thus Congress did not intent to preempt the field with its 340B legislation.

Taking Plaintiff's allegation as true for the purpose of a motion to dismiss, Plaintiff fails to state a claim upon which relief can be granted given this circuit's precedent in *McClain.* For the reasons stated herein, Defendants' Motion to Dismiss Count III as it relates to field preemption is **GRANTED**.

B. Conflict Preemption

Plaintiff argues that S.B. 751 is conflict preempted because Congress placed strict limits on the types of entities entitled to 340B pricing and the types of patients that may receive drugs sold at a 340B price. (Complaint ¶ 144). Plaintiff states Congress provided that only "covered entities' are eligible to receive 340B pricing, and it expressly defined that term to include only fifteen enumerated types of medical facilities to which contract pharmacies are not one. *Id*. Plaintiff asserts the 340B statue does not expressly allow covered entities to transfer drugs to retail

pharmacies or require manufacturers to engage in such transfers on behalf of covered entities. (Complaint ¶ 145). Plaintiff alleges that S.B. 751 requires drug manufactures to transfer drugs at 340B prices to pharmacies that maintain a contract with a covered entity without regard to whether those drugs will ultimately be dispensed to any patient of a covered entity. (Complaint ¶ 146).

As discussed previously, the Eighth Circuit ruled in *McClain* that the Arkansas law did not require manufactures to provide 340B pricing discounts to contract pharmacies nor does the state statue set or enforce discount pricing revealing no obstacle to the enforce of the 340B program. *McClain at 1145.* Here, S.B. 751 does the exact same. S.B. 751 does not require manufacturers to extend the federal 340B discount to contract pharmacies, it just restricts pharmaceutical companies from infringing on the distribution and delivery of 340B drugs bought by covered entitles utilizing the 340B program. S.B. 751 does not set or enforce discount pricing but protects covered entities use of contract pharmacies. As such, there is no obstacle to the enforcement of the 340B program. Consistent with the precedent set by the Eighth Circuit, Plaintiff has failed to allege a claim upon which relief can be granted. For the reasons stated, Defendants' Motion to Dismiss Count III as it relates to obstacle preemption is **GRANTED**. Count III is **DISMISSED** in its entirety.

IV. Count IV – Unconstitutional Extraterritorial Regulation

Court IV seeks declaratory and injunctive relief that S.B. 751 is unconstitutional as it is an unconstitutional extraterritorial regulation. Specifically, Plaintiff argues much of the conduct regulated by S.B. 751 will occur beyond Missouri boarders and will operate even where the transactions occur out-of-state and involve only-out-state actors. Court IV cites the Commerce Clause, Article IV §§ 1-3, the Due Process Clause, and the Commerce Clause of the United States Constitution in support of its unconstitutional extraterritorial regulation argument. Defendants argue that S.B. 751 does not apply extraterritorially and even so S.B. 751 does not directly regulate

transactions taking place wholly outside the state and involving individuals having no connection with the state.

A. The Contracts Clause, Article IV §§ 1-3, and the Due Process Clause of the Constitution

The Contract Clause of the United States Constitution provides that no state shall "pass any law impairing the Obligation of Contracts." U.S. Const. art. I, § 10, cl. 1. Article IV. § 1 of the United States Constitution represents the Full Faith and Credit clause. U.S. Const. art. IV. Article IV, §§ 2-3 of the United States Constitution covers the Privileges and Immunities clause, and clause for admitting new states. The Due Process Clause of the United States Constitution as applied through the fourteenth amendment provides that no person shall be deprived of life, liberty, or property, without due process of the law. U.S. Const. amend. V.

Taking as true Plaintiff's allegations for the purpose of a motion to dismiss, it has failed to raise its right to relief above a speculative level. Plaintiff's Complaint provides no facts that would allege a Contract Clause violation, Article IV violation, or a Due Process clause violation. Plaintiff's complaint merely states "states are denied certain powers that a sovereign might ordinarily impose, U.S. Const. art. I. § 10; and required to honor certain rights of other states, U.S. Const. art. IV. §§ 1, 2, 3." (Complaint ¶ 150). "Similarly, the Due Process clause limits a state's ability to regulate conduct occurring wholly outside its borders." Id. "S.B. 751 is unconstitutional under these principles. (Complaint ¶ 151). To the extent that Plaintiff attempts to make an unconstitutional extraterritorial argument under any of these provisions under the Constitution, it has failed to list any factual allegation that would warrant serious consideration. For the reasons stated, Defendants' Motion to Dismiss Count IV – Unconstitutional Extraterritorial Regulation as to the Contracts Clause, Article IV, and Due Process Clause claims are **GRANTED**.

B. Commerce Clause

The Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside of the state's borders, whether or not the commerce has effects within the state. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989). A statute directly controlling wholly out-of-state commerce "is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id*. However, there is no per se rule under the dormant Commerce Clause forbidding enforcement of state laws that have the practical effect of controlling commerce outside the State, when those laws do not purposely discriminate against out-of-state economic interests. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 143 S. Ct. 1142, 1159, 215 L. Ed. 2d 336 (2023).

For the purposes of a motion to dismiss, Plaintiff has alleged facts that raise a right to relieve above a speculative level. Plaintiff alleges S.B. 751 broadly bans all pharmaceutical manufacturers, many of whom have no physical presence in Missouri, from denying, restricting, or prohibiting, either directly or indirectly, a contract pharmacy's acquisition of a 340B drug. (Complaint ¶ 151). This will apply to out-of-state transactions between out-of-state manufacturers and out-of-state distributors. (Complaint ¶ 152). Likewise, it will apply to out-of-state transactions between out-of-state manufacturers or out-of-state distributors, on one side, and out-of-state covered entities. *Id*. In sum, S.B. 751 will operate even where the transactions occur out-of-state and involve only out-of-state actors. *Id*. These allegations are sufficient at this stage of the litigation to continue. For the reasons stated, Defendants' Motion to Dismiss on Count IV – Unconstitutional Extraterritorial Regulation as to the dormant Commerce Clause is **DENIED**.

CONCLUSION

For reasons herein, Defendants' Motions to Dismiss are **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motions to Dismiss Count I are **GRANTED**. Defendants' Motions to Dismiss Count II are **GRANTED.** Defendants' Motions to Dismiss Count III are **GRANTED**. Defendants' Motions to Dismiss Count IV as to the Contracts Clause, Article IV §§ 1-3, and Due Process Clause arguments are **GRANTED** and as to the Commerce Clause is **DENIED**.

IT IS SO ORDERED.

DATED: February 27, 2025

/s/ Douglas Harpool
DOUGLAS HARPOOL
UNITED STATES DISTRICT JUDGE